Remarks

Claims 24-42 and 44 are pending in the subject application. Applicant acknowledges that claim 27 has been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicant has canceled claims 40, 42 and 44, amended claims 24, 26, 39 and 41 and added new claims 45-56. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, pages 11-15 and Examples 4 and 6. Entry and consideration of the amendments presented herein is respectfully requested. Applicants further request that the Supplemental Information Disclosure Statement that accompanies this response be considered by the Examiner. Accordingly, claims 24-39, 41 and 45-56 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 24-26, 28-42 and 44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 24-26, 28-42 and 44 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action acknowledges that the specification is enabled for an *in vitro* method of inhibiting the proliferation of MBP specific T cells induced by AC1-11 comprising contacting said cells with soluble CD164 polypeptide, but is not enabled for a method of treating any "inflammatory and/or autoimmune diseases" comprising the administration of a composition comprising a soluble protein comprising a sequence having at least "85% of homology with the mature form of the extracellular domain of human CD164 (SEQ ID NO:1)", wherein said soluble protein is an "active mutein or an isoform of SEQ ID NO:1", wherein said soluble protein is an "active derivative, a proteolysis-resistant modified form, a conjugate, a complex, a traction, a precursor, and/or a salt", wherein said inflammatory and/or autoimmune disease is multiple sclerosis, or a method of inhibiting the expression of one or more cytokines in an individual comprising administering to said individual a composition comprising a soluble protein comprising a sequence having "at least 85% of homology with the mature form of the extracellular domain of human CD 164 (SEQ ID NO:1)", wherein said cytokine is TNF-α, IFN-γ, IL-2, IL-4, IL,-5, or IL-10. The Office Action also argues that the as-filed specification fails to enable the claimed

methods of treatment (*in vivo*) and provides a number references supporting its arguments that animal models are not considered predictive of the results obtained in humans with respect to the treatment of multiple sclerosis. Applicant respectfully asserts that there is adequate written description in the subject specification to convey possession of the claimed invention to the skilled artisan and that the claims are enabled by the subject specification.

Turning first to the enablement rejection, Applicant respectfully submits that a focus on the clinical failure of therapeutic compounds for treating multiple sclerosis that were identified via the EAE animal model is an insufficient basis for rejecting the claims of this matter where they are directed to methods of treating multiple sclerosis (MS). As noted by Baker and Jackson, MS appears to be a uniquely human condition and no other animal spontaneously develops a disease identical to MS. Further, the authors indicate that while EAE may be an imperfect model, it has been used to shape therapeutic approaches for the treatment of MS for decades and the failure to detect viable treatments may be the result of how studies are interpreted by the scientific and medical community (see page 10, column 2, last paragraph). Baker and Jackson also indicate that EAE is a leading research tool for the identification of MS therapies (see page 11) and that while a number of agents shown to ameliorate EAE have failed in the clinic, the development of drugs such as Tysbari have been critically dependent upon such animal models (page 11, column 3, last paragraph). Additionally, Steinman and Zamvil (*Ann. Neurol.*, 2006 60:12-21) discuss how one can successfully apply EAE models to MS. Indeed, the reference indicates that EAE has lead to the development of three therapies for MS and several new approaches for the treatment of MS are in clinical trials based upon positive results obtained in the EAE model (see Abstract). Steinman and Zamvil also discuss problems and promise surrounding the use of EAE models for the development of therapies for MS (see pages 16-19). Here, it is indicated that there is a long list of drugs that have shown promise in EAE models that are now being taken forward into the clinic. Other approaches, such as sphingosine inhibitors, statins, carboxamido and an IL-2 monoclonal antibody have shown promise in phase 2 trials and were first based upon success in the EAE model (page 16, column 1, paragraph 1). Thus, it is respectfully submitted EAE models are art recognized acceptable models for the identification of candidate compounds for the treatment of MS. Regarding the alleged lack of teaching with respect to the relationship of the MBP specific T-cells activated by the Ac1-11 peptide, Example 5 indicates

that the claimed polypeptide is able to inhibit the proliferation of MBP specific T-cell clones, cells recognized to be a target for MS therapies. Thus, Applicant respectfully submits that the ability of the claimed polypeptide to inhibit proliferation of MBP specific T-cells would have indicated that the claimed polypeptide was a candidate compound suitable for the treatment of MS and those skilled in the art would have known how to use such a candidate compound in view of the state of the art at the time the invention was made.

With respect to the issues raised with regarding claims 41 and 42, Applicant respectfully submits that the Office Action improperly rejects these claims as related to the treatment of MS. Applicant respectfully submits that the claims are directed to methods of reducing the production TNF-α, IL-2, IFN-γ, IL-6, IL-5 and IL-10. The as-filed specification clearly indicates that the claimed polypeptide is capable of reducing the expression of these cytokines by cells (see Example 2 and Example 6). Accordingly, it is respectfully submitted that this aspect of the invention is enabled and reconsideration of this rejection is respectfully requested.

Turning to the issue raised with respect to the written description of the claimed invention, Applicant respectfully submits that the as-filed specification provides adequate description of the claimed invention such that one skilled in the art would have recognized that Applicant was in possession of the claimed invention, particularly in view of the claim amendments presented herewith regarding the treatment of multiple sclerosis. With respect to the written description issue raised regarding polypeptides having a specified percentage of identity to SEQ ID NO: 1, Applicant respectfully submits that various isoforms of the CD164 polypeptide were known at the time the application was filed as were functional domains and motifs of the CD164 polypeptide (see paragraph bridging pages 5-6 and Chan *et al.* (Ref. R9 of the IDS submitted August 28, 2006 at pages 2142-2143 and 2146-2147)). As the Patent Office is aware, the written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). Additionally, the courts have noted that there is no "per se rule that the information must be

information related to a given biological molecule is available in the prior art. *See Capon v. Eshhar*, 76 USPQ2d 1078, 1084-1085 (Fed. Cir. 2005). Thus, it is respectfully submitted that the written description requirement of section 112 is met by the combined physical and functional characteristics of the soluble protein recited in the claims coupled with the knowledge in the art with respect to the CD164 polypeptide. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

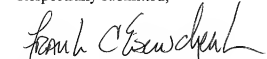
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position. Applicant expressly reserves the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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